# UK Patent Application GB GB G 2 095 119 A

- (21) Application No 8138238
- (22) Date of filing 18 Dec 1981
- (30 Priority data
- (31, 246995
- (32) 24 Mar 1981
- (33) United States of America
  (US)
- (43) Application published 29 Sep 1982
- (51) INT CL<sup>3</sup> A61F 1/16
- (52) Domestic classification A5R AE
- (56) Documents cited GB 1522401 GB 1044420
- (58) Field of search A5R
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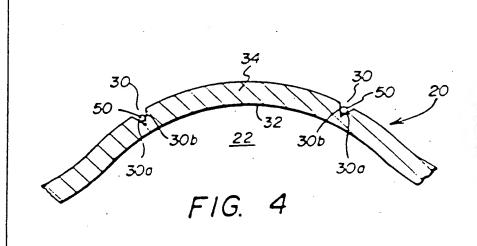
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- (54) Circular keratotomy with insert for myopia correction
- (57) A space maintainer (e.g. ring) (50) is provided for use in a circular keratotomy surgical procedure. Space maintainer (50) is inserted in an

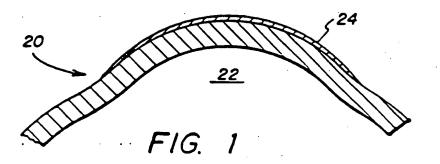
incision (30) cut into the cornea (20) of an eye (22) of a patient. The incision (30) circumscribes the optical zone (32) of the eye (22) to cause the cornea (20) to flatten (34). Space maintainer (50) maintains the cornea (20) in the flattened position (34).

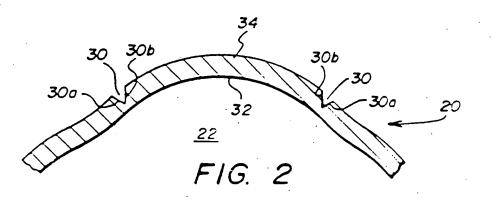
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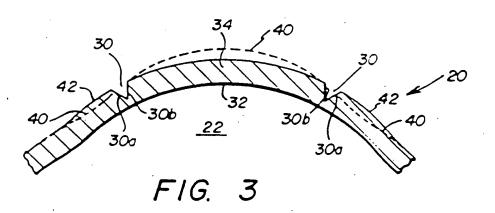
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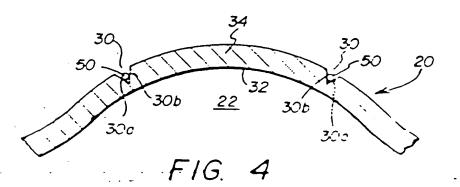


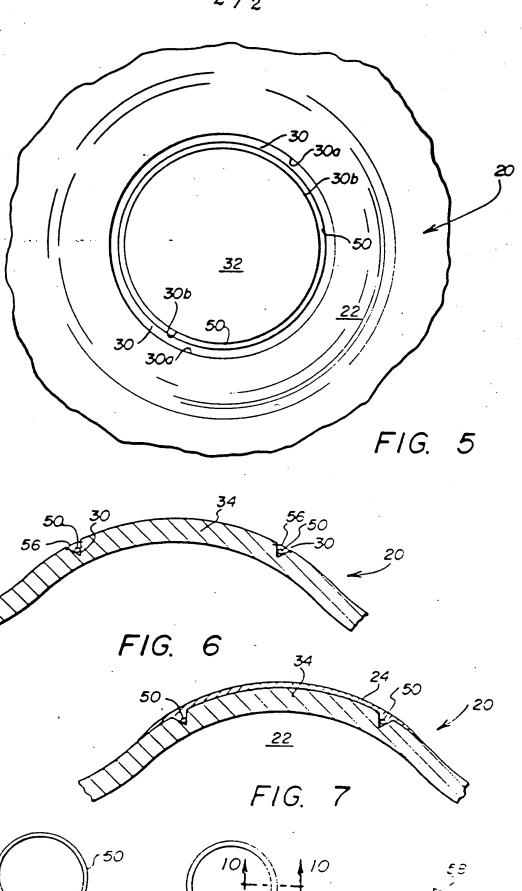
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SPECIFICATION
Circular keratotomy with insert for myopia correction

#### Technical Field

This invention relates to corrective eye surgery, and more particularly to circular keratotomy and an insert for myopia correction.

#### Background Art

The process by which one visually perceives
10 involves light entering the eye in parallel rays,
which are generally bent as they pass through the
cornea and lens of the eye. In the normal eye, the
light rays converge, or focus, on the retina at the
back of the eyeball. Electrical impulses then
15 transmit a sharp image to the brain.

A common vision problem involving an improperly shaped eyeball is nearsightedness (myopia). In the nearsighted vision problem, the eyeball is usually too long or the cornea too curved, so that the light rays entering the eye come to a focal point in front of the retina. Eyeglasses and contact lenses change the focal point of the light entering the eye to provide

corrected vision for nearsighted vision problems. Another approach to correct nearsightedness is 25 to change the curvature of the cornea so that images fall directly on the retina. A corneal operation termed radial keratotomy has been used by Dr. Svyatoslav Fyodorov of Moscow, Russia. In 30 Dr. Fyodorov s procedure fourteen to sixteen radial cornea incisions are made of varying length and depth into the cornea of an eye. The incisions extend from the outer edge of the cornea towards the center of the cornea. These incisions induce 35 peripheral cornea staphyloma resulting in central corneal flattening. This flattening causes the curvature of the cornea to be reduced which in turn compensates for axial myopia.

Although radial keratotomy comprises a 40 relatively simple surgical operation and has been shown to provide an average correction of about 1.9 diopters, it has been found that such correction is temporary. It has been found that in many cases, the cornea returns to its original 45 curvature and the original error in vision returns. It has also been found that the radial incisions are difficult to control in length and depth since the incision is through almost nine-tenths of the cornea's thickness. These incisions introduce a 50 risk of perforation of the cornea during surgery. Furthermore, it has been found that the radial incisions cause the patient to experience glare sensitivity for night vision since the radial incisions are made close to the optical zone of the eye.

keratotomy procedures for the correction of myopia vision problems in which improved long-term vision correction is achieved. Furthermore, a need has arisen for improved keratotoms.

60 procedures in which the corneal incisions are controlled to minimize the risk Clipanore; an extraction and corneal Alberta has further arisen for a keratotic minimizer.

procedure in which corneal into onsian

A need has thus developed for improved

55

positioned away from the optical zone of the eye 65 to reduce patient glare sensitivity.

#### Disclosure of the Invention

In accordance with the present invention, a circular keratotomy procedure is provided together with an insert for substantially eliminating the 70 problems heretofore associated with radial keratotomy.

In accordance with the present invention, a space maintainer for use in corneal keratotomy wherein an incision is made into the cornea of a patient, the incision circumscribing the optical zone of the eye to cause the cornea to flatten is provided. The space maintainer includes a ring for insertion into the circular incision for maintaining the cornea in the flatted position.

In accordance with another aspect of the present invention, a method for the surgical correction of myopia is provided. The method includes the step of cutting an incision into the cornea of a patient wherein the incision

85 circumscribes the optical zone to cause the cornea to flatten. A spacer is inserted into the incision for maintaining the cornea in the fattened position.

#### Brief Description of the Drawings

For a more complete understanding of the 90 present invention and for further advantages thereof, reference is now made to the following Detailed Description taken in conjunction with the accompanying Drawings, in which.

FIGURE 1 is a cross-sectional view of a cornea;
95 FIGURE 2 is a cross-sectional view of the cornea of FIGURE 1 with the epithelial layer removed and a circular incision made according to the present invention;

FIGURE 3 is a cross-sectional view, of the 100 cornea of FIGURE 2 wherein central corneal flattening is illustrated.

FIGURE 4 is a cross-sectional view of the cornea of FIGURE 3 illustrating the insent of the present invention disposed within the circular incision;

FIGURE 5 is a top plan view of the cornea illustrated in FIGURE 4.

FIGURE 6 is a cross-sectional view of the cornea of FIGURE 4 illustrating the incision having 110 been sutured:

FIGURE 7 is a cross-sectional view of the cornea of FIGURE 6 and a newly grown epithelia-layer:

FIGURE 8 is a top plan view of an embodiment 115 of the present insert:

FIGURE 9 is a topical view of an atternate embeddment of the insert of the divisors project in and

FIGURE 10 is a cross-section allowing on 120 generally arong sections in en 10 — 10 cross insert illustrated in Figure 3.

Detailed Investment FIGURE 1 to the present invention. Cornea 20 includes epithelial layer 24.

FIGURE 2 illustrates eye 22 with epithelial layer 24 removed. A circular groove 30 is cut in cornea 5 20 to a depth of approximately 0.2 to 0.7 millimeters. Circular groove 30 circumscribes the optical zone, generally identified by the numeral 32 of eye 22 and has a diameter of approximately eight millimeters. It therefore can be seen that 10 circular groove 30 is disposed away from optical zone 32 to eliminate glare sensitivity heretofore associated with radial keratotomy procedures.

- Circular groove 30 has a width of approximately 0.2 millimeters and is defined by sidewalls 30a and 30b. Circular groove 30 can be formed using a corneal trephine in which the depth of cut can be precisely controlled.

FIGURE 3 illustrates the results of the incision of circular groove 30 within cornea 20. The incision of circular groove 30 in cornea 20 induces peripheral cornea staphyloma resulting in central corneal flattening in the area of optical zone 32. The curvature of cornea 20 in the area of optical zone 32 is reduced to thereby compensate for

axial myopia. In comparing FIGURES 2 and 3, it can be seen that central corneal area 34 of cornea 20 has flattened from the position illustrated in FIGURE 2. This initial position is illustrated in FIGURE 3 via the dotted line 40. It can also be
 seen in FIGURE 3 that peripheral portions 42 or

cornea 20 have protruded above their initial position, being higher than line 40. The flattening of central corneal area 34 results in the shortening of eye 22 to correct for myopia and in a flatter and therefore optically weaker cornea.

Referring simultaneously to FIGURES 4 and 5, the insert of the present invention is illustrated, and is generally identified by the numeral 50. Insert 50 is disposed within circular groove 30 for maintaining sidewalls 30a and 30b of circular groove 30 apart during healing of the incision which forms circular groove 30. Insert 50 forces and maintains sidewalls 30a and 30b apart until sufficient scarring tissue closes circular groove 30.

45 to thereby maintain central corneal area 34 of cornea 20 in the flattened position shown in FIGURE 3. Insert 50 may comprise, for example nylon, extruded PMMA, polypropylene or similar materials.

FIGURE 6 illustrates the use of sutures 55 for temporarily maintaining insert 50 in place within circular groove 30 during healing of the incision forming circular groove 30.

FIGURE 7 illustrates insert 50 permanently in place by normal scarring which has taken place between sidewalls 30a and 30b of circular groove 30. FIGURE 7 further illustrates a newly grown epitheliai layer 24.

FIGURE Slittustrates insert 50 in greater betain 60. Insert 50 comprises a circular ring having a

diameter of approximately eight millimeters. Circular ring 50 has a circular cross-sectional area having a diameter of approximately 0.1 to 0.5 millimeters.

FIGURE 9 illustrates an insert 58 for insertion into circular groove 30 (FIGURE 4) having a configuration similar to insert 50. Insert 58 has a triang: ar cross-sectional area as illustrated in FIGUR: 10 for more closely matching sidewalls
 30a and 30b of circular groove 30 when inserted. The length of a side of insert 58 is approximately 0.3 millimeters.

It therefore can be seen that the present circular keratotomy for myopia correction provides 75 for a circular incision circumscribing the optical zone of an eye. The circular incision is disposed away from the optical zone to avoid glare sensitivity heretofore present with radial . keratc:omy surgical procedures. The depth of the 80 circular incision and the diameter of the incision ... control the amount of central cornea flattening and the resulting correction. The present invention further provides for an insert for maintaining the cornes in a flattened position to prevent the 85 cornes from returning to its original error. The insert maintains the incision open thereby permitting corneal flattening until normal scarring takes piace.

Whereas the present invention has been described with respect to specific embodiments thereof, it will be understood that various changes and modifications will be suggested to one skilled in the amand it is intended to encompass such changes and modifications as fall within the scope of the appended claims.

#### CLA: U.S.

 A space maintainer for use in corneal keratotomy wherein an incision is made into the cornea of a patient, the incision circumscribing the 100 optical zone of the eye to cause the cornea to flatter comprising:

means for insertion into the circular incision for maintaining the cornea in the flattened position.

- 2. The space maintainer of Claim 1 wherein 105 said means for insertion comprises ring means
  - 3. The space maintainer of Claim 2 wherein said ring means has a circular cross-sectional area.
- The space maintainer of Claim 2 wherein
   Said ring means has a triangular cross-sectional area.

5. 4 method for surgical correction of myopia comprising the steps of:

cutting an incision into the cornea of a patient 115 circumscribing the optical zone thereby causing the cornea to flatten, and

inserting a spacer linto the incision for maintaining the corneal in the flattered pool tion to 6. A space maintainer for use in corneal



keratotomy substantially as herein described with reference to and as illustrated by the accompanying drawings.

7. A method for surgical correction of myopia 5 substantially as herein described with reference to and as illustrated by the accompanying drawings.

Printed for Her Majesty's Stationery Office by the Courier Press, Learnington Spa. 1982. Publicated by the Patent Office.

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